Chapter 2: Guide to Issue Discussions

2.1 Introduction

As addressed in Chapter 1, the scope of this document covers three critical components of the overall site assessment and remediation process exposure assessment, toxicity assessment and risk characterization. When combined with site data collection and evaluation these analytical elements constitute the baseline risk assessment This chapter serves as a guide to the information presented in the body of this report. It will help the reader identify specific information pertaining to those components of the BRA that should be discussed with regulators prior to finalizing project-specific baseline risk assessment methodologies.

Figure 2.1 outlines which baseline risk assessment components are discussed in each chapter. As shown in this figure, the majority of chapters deal with the exposure assessment component. This is because most potentially negotiable analytical issues apply to that segment of the BRA process. Considerably more resources may be required to negotiate toxicity assessment issues than issues associated with either the exposure assessment or risk characterization. That is because these negotiations will require the assistance of an experienced toxicologist.

This chapter is divided into four sections. The first three sections outline the issues related to the following components of the baseline risk assessment process exposure assessment, toxicity assessment, and risk characterization. These sections also outline the chapter in which each issue is discussed. The final section of this chapter lists key words that are associated with each of the issues, and points the reader to the specific section(s) of the document that discuss that keyword. The organization of this section assures that readers of this document rapidly can locate a given subject of interest either by the subject heading or by pertinent keywords.

2.2 Issues Pertaining to Exposure Assessment

Many of the controversial issues in risk assessments are associated with exposure assessment, and it is recommended that attempts at risk assessment methodology negotiation begin with this component Figure 2.2 outlines the issues that apply to exposure assessments and the chapters in which these issues are discussed. Following is an overview of each issue. Please refer to the appropriate chapter for a more comprehensive discussion of these issues.

Figure 2.1 Correspondence Between BRA Components And Chapters in This Guidance

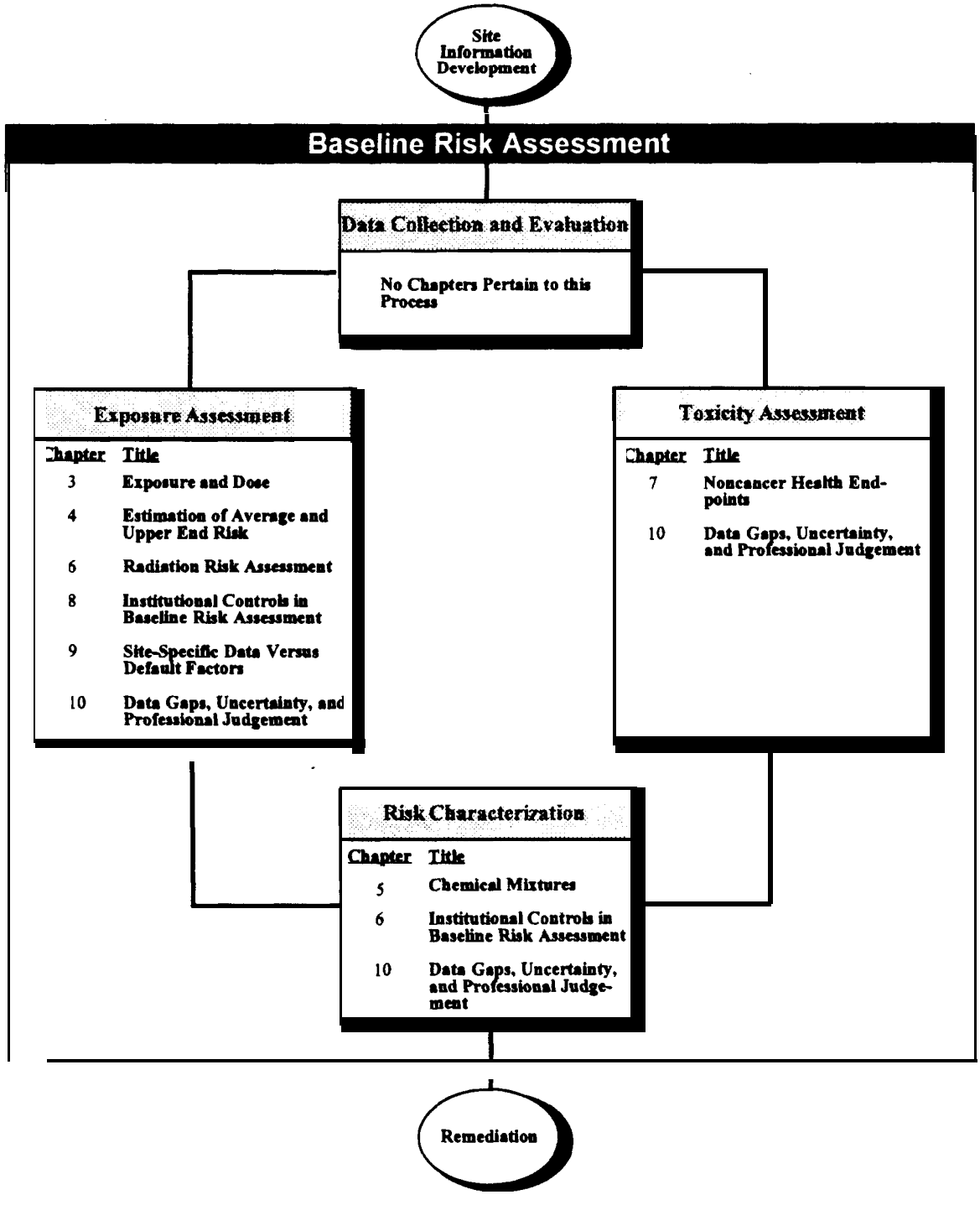

Figure 2.2: Issues Pertaining to Exposure Assessment

Chapter 3: Exposure and Dose	
Issue 1:	Exposure/Dose Terminology
Issue 2:	Exposure/Dose Calculations
Chapter 4: Estimation of Average and Upper End Risk	
Issue 1:	Risk Descriptors (e.g., RME)
Issue 2:	Professional Judgement
Chapter 6: Radiation Risk Assessment	
Issue 1:	Exposure Calculations
Issue 2:	Radionuclide Progeny
Chapter 8: Institutional Controls	
Issue 1:	Evaluation of Institutional Controls
Issue 2:	Exposure Scenario Development
Chapter 9 Site Specific Data vs. Default Factors	
Issue 1:	Use of Site Specific Data
Issue 2:	Use of Default Factors
Chapter 10: Data Gaps, Uncertainty, and Professional Judgement	
Issue 1:	Sources of Uncertainty
Issue 2:	Impact of Data Gaps on Risk Estimate
Issue 3:	Means to Address Uncertainty

2.2.1 Exposure and Dose

Issue 1: Exposure/Dose Terminology

Exposure and dose terminology are discussed in Chapter 3. These definitions have changed over the years. Originally, exposure was quantified by measuring or estimating the amount of a chemical at the exchange boundaries (i.e., lungs, gut, skin) during some specified time period. The current concept of exposure and dose is delineated in the Guidelines for Exposure Assessment (USEPA 1992a). Exposure is defined as contact of a chemical, physical, or biological agent with the outer boundary of an organism:

that is, the skin, mouth, or nostrils. There are six different terms used for close: administered, potential, applied, absorbed, internal, and delivered. See Chapter 3 for a definition on each of these terms.

Issue 2: Exposure/Dose Calculations

The change in definitions has resulted in some confusion in how exposures and dose are calculated. In the original definition, exposure was equivalent to the administered doses given in animal experiments (i.e., the exposure equation included the intake rate for inhalation or ingestion). The current concept of exposure, however, is the concentration of the substance in the medium (e.g., soil, air, water) integrated over the time duration of the contact. The exposure must be multiplied by the intake rate to calculate the amount of substance at the exchange boundaries (i.e., gut lung and skin). This calculation is performed so that exposures become equivalent to the administered dose given in animal experiments. Dermal exposure estimates have always included the amount of substance absorbed through the skin because it is known that dermal and internal absorption (i.e., gut and lung) occur at different rates, and the skin acts as both an outer boundary and an exchange boundary.

Regulator Dialogue

It is vital that DOE and the regulator fully understand the assumptions inherent in these definitions as those assumptions affect the way exposure is calculated.

2.2.2 Estimation of Average and Upper End Risk

Issue 1: Risk Descriptors

As guidance for conducting risk assessments has evolved over the years, various loosely defined descriptors (such as reasonable worst case, worst case, and maximum exposed individual [MEI]) have been used to describe the upper-end exposure scenario. Chapter 4 describes the development of these risk descriptors. Often these risk descriptor terms were poorly defined in the guidance documents, and guidance was often unclear as to how exposure should be calculated under these various exposure conditions. The current risk descriptor used is reasonable maximum exposure (RME).

Issue 2: Professional Judgement

Because the risk descriptor terms were loosely defined, it was left to the "professional judgement" of the assessor to choose how to calculate upper-end exposure. When site-specific information was not available, the risk assessor used professional judgement to choose the various default factors used in calculating the RME. For example, the RME is now calculated by combining 95% upper confidence limit values with 50th and 90th percentile values for some of the default values, but specific guidance was never given as to which values should be 50th or 90th percentile.

Regulator Dialogue

The professional judgement used by DOE, so long as it is reasonable and defensible, should be acceptable to the regulatory personnel. Assessors may negotiate which default factors and chemical concentration values are to be used. The Science Advisory Board (SAB) is recommending the use of frequency distribut ions to calculate the variables used in the exposure equations. Assessors may also negotiate the use of such techniques (e.g., Monte Carlo simulation) with EPA.

2.2.3 Radiation Risk Assessment

Issue 1: Exposure Calculations

Chapter 6 discusses two aspects of radiation risk that must be considered in the exposure assessment. The first aspect to consider is what type of radiation risk (alpha, beta, or gamma) is being calculated. Gamma radiation is important both internally and externally. Because gamma radiation is an external penetrating source, this type of exposure must also be considered with gamma emitters. Alpha and beta emitters are only important for internal exposures. Alpha or beta radionuclide must be absorbed into the body before they can exert their deleterious effects. This is also true for dermal exposures The alpha or beta emitter must be absorbed through the skin before this exposure scenario can be considered.

Issue 2: Radionuclide Progeny

The second aspect to consider in exposure assessments with radiation risk is radionuclide progeny. Radionuclide decay to produce other radionuclides that will have different half lives, and possibly different types of radiation. Some of the progeny may have long half lives, while others may have very short half lives, on the order of days or hours. Exposure to all of the progeny must be considered in the risk assessment.

Regulator Dialogue

Radiation exposures behave as a continuum. As the parent radionuclide decays the progeny can change to a different type of emitter (i.e., alpha, beta, or gamma), and therefore the exposure route of concern may also change. Because some of the radionuclide have a long half life, the parent compound along with its progeny can exist at a site at the same time. DOE and regulatory personnel must be aware of which radionuclide are involved at the site at present, what type of radiation they emit, what their half lives are, and how this will change over time.

2.2.4 Institutional Controls

Issue 1: Evaluation of Institutional Controls

Institutional controls in risk assessments are discussed in Chapter 8. It is clear from NCP and the various risk assessment guidelines that institutional controls cannot be considered as part of the baseline

risk assessment- The risk-reduction implications of existing institutional controls only can be considered as part of the remedial action plan.

Issue 2: Exposure Scenario Development

A related topic discussed in Chapter 8 is land-use development. The default land-use scenario for risk assessments is residential. The guidelines state that if another land use is reasonable, then that land use can be used.

Regulator Dialogue

If DOE is going to retain control of a site, then industrial land use can reasonably be assumed in assessing exposure in the baseline risk assessment. Industrial land-use scenarios can usually reduce the risks in the risk assessment as compared with residential scenarios.

2.2.5 Site-Specific Data Versus Default Factors

Issue 1: Use of Site-Specific Data

Baseline risk assessments are conducted using both site-specific data and default factors. Chapter 9 discusses this issue. All of the exposure guidelines state that site-specific data are preferable to default factors, but complete site-specific data are never available, particularly with respect to environmental fate, transport, and human behavior patterns.

Issue 2: Use of Default Factors

Professional judgement is used to determine which default factors and exposure models are the most appropriate for a particular site. Typically, the standard &fault factors are conservative, and the overall exposure assessment potentially can become overly conservative when the default factors are compounded together.

Regulator Dialogue

Assessors can negotiate which factors and models are the most appropriate to use in the assessment. It is to DOES advantage to gain as much site-specific information as possible. More site-specific information results in less conservative default factors and models being used in the risk assessment. This will also reduce the amount of negotiation needed with respect to the use of default factors and models.

2.2.6 Data Gaps, Uncertainty, and Professional Judgement

Issue 1: Sources of Uncertainty

All risk assessments involve some data gaps, which must be resolved through professional judgement. This, however, may result in greater uncertainties being introduced into the assessment. Chapter 10 discusses how data gaps, uncertainty, and professional judgement affect the various components of the risk assessment. As stated above, typically some site-specific information is missing from any exposure assessment. The gaps are filled with models and default factors chosen by the assessor using professional judgement, but there is always uncertainty attached to such data and models. In fact, there are six basic sources of uncertainty in exposure assessment measurement errors, indirect empirical or generic data, variability of natural systems, environmental modeling, sampling errors, and professional judgement.

Issue 2: Impact of Data Gaps on Risk Estimate

As stated above, data gaps are filled with models and default factors. Chapter 10 points out that these models and default factors are usually conservative, and therefore they normally overestimate the risk. Minimizing the use of models and default factors will help to minimize the overestimation of the risk.

Issue 3: Means to Address Uncertainties

There are various means to address the uncertainty inherent in risk assessments. More site-specific data can be collected to reduce data gaps. Also, as the science of exposure assessment is improved, better models will be produced thereby reducing uncertainty.

Regulator Dialogue

Both the models and default factors used can be negotiated with EPA.

2.3 Issues Pertaining to Toxicity Assessment

The fewest and most resource-intensive negotiable issues are associated with the toxicity assessment. The toxicity values used in the risk assessment come from peer-reviewed sources. It will require the assistance of an experienced toxicologist to challenge these peer-retie wed value-s. It is recommended that the toxicity assessment be the last component of the baseline risk assessment that is negotiated. Figure 2.3 illustrates the chapters and the issues addressed herein that apply to toxicity assessments. This section will give a brief discussion of each issue. The reader is referred to the appropriate chapter to gain a full understanding of these issues.

Figure 2.3: Issues Pertaining to Toxicity Assessment

Chapter 7: Noncancer Health Endpoints	
Issue 1:	Alternative Toxicity Values
Issue 2:	Alternative Toxicity Study Requirements
Chapter 10: Data Gaps, Uncertainty and Professional Judgement	
Issue 1:	Sources of Uncertainty
Issue 2:	Impact of Uncertainty on Risk Estimates
Issue 3:	Means to Address Uncertainty

2.3.1 Noncancer Health Endpoints

Issue 1: Alternative Toxicity Values

Alternative toxicity values and the types of studies that can be used to generate these values are discussed in Chapter 7. Both the regulations (USEPA, 1990a) and the guidelines USEPA 1989a) indicate that alternative toxicity values may be considered by EPA. There are generally three reasons to present new toxicity values:

- if there are no existing value(s) in the Integrated Risk Information System (IRIS),
- if the value in IRIS is assigned a low confidence, or
- to evaluate the estimation of risk using existing values in IRIS (according to EPA, "other information, such as additional toxicity information, may be evaluated to determine whether the risks are likely to have been under- or overestimated" [USEPA, 1989a]).

Issue 2: Alternative Toxicity Study Requirements

There are several requirements that any new study must meet for EPA to seriously consider the new study. The study must have a better design than the previously accepted investigation. This may include a more relevant animal model backed by the appropriate biological and/or pharmacokinetic data, a dosing regime that follows prescribed protocols, and a route of administration that is appropriate for the expected human exposure. In general, the new research must produce a higher level of confidence in the data than the previously accepted study. It is also important for the new study to provide a clearer interpretation of the results. If the new investigation does not produce any more lucid results, then EPA will probably not accept the new results.

Regulator Dialogue

As stated in Sections 2.1 and 2.3.1, the toxicity assessment will be the most difficult component to negotiate. It is recommended that negotiations on toxicity values not be attempted unless DOE has compelling evidence to change a value.

2.3.2 Data Gaps, Uncertainty, and Professional Judgement

Issue 1: Sources of Uncertainty

As discussed in Section 2.2.7, data gaps and uncertainty area natural part of all risk assessments, including the toxicity assessment component. Sources of uncertainty include the animal experiments and their associated uncertainties in the choice of the animal model, study design, interpretation of the results, and extrapolating from high to low doses and from animals to humans.

Issue 2: Impact of Uncertainty on Risk Estimates

The assumptions used in toxicity experiments and data extrapolation normally produces overestimation in the risk.

Issue 3: Means to Address Uncertainty

The uncertainties can be reduced by choosing better animal models, using human epidemiological data if available, and applying better extrapolation models.

Regulator Dialogue

Both the models and default factors used can be negotiated with EPA.

2.4 Issues Pertaining to Risk Characterization

Risk characterization is the step where information from the exposure and toxicity assessments are combined to project the potential risk posed by a hazardous waste site. There are issues related to combining these two steps to produce the risk calculation, which are outlined in Figure 2.4. This section will give a brief discussion of each issue. Please refer to the appropriate chapter to gain a more comprehensive understanding of each issue.

Figure 2.4 Issues Pertaining to Risk Characterization

Chapter 5: Chemical Mixtures	
Issue 1:	Dose Additivity
Issue 2:	Impact of Summing HQs
Chapter 10: Data Gaps, Uncertainty, and Professional Judgement	
Issue 1:	Sources of Uncertainty
Issue 2:	Impact of Uncertainty on Risk Estimates
Issue 3:	Means to Address Uncertainty

2.4.1 Chemical Mixtures

Chemical mixtures are defined as any combination of two or more chemical substances. The mixture may be purposely formulated (such as gasoline or pesticides), or the chemicals may have been combined inadvertently through improper disposal. Chapter 5 discusses how risks are calculated for chemical mixtures.

Issue 1: Dose Additivity

Although the guidelines recommend that toxicological information on the specific chemical mixture of interest be used to calculate risks, toxicological information on chemical mixtures is rarely available. Therefore, EPA recommends using dose additivity in the absence of specific data. Dose additivity assumes that the chemicals have the same mode of action and elicit the same effects, an assumption that may not reflect reality. The dose additivity assumption also ignores antagonistic or synergistic interactions. If the chemicals act synergistically, then the calculated risk will underestimate the actual risk; if the chemicals act antagonistically, then the calculated risk will overestimate the actual risk.

Issue 2: Impacts of Summing HQs and Slope Factors

For noncarcinogens, an estimation of risk is determined by calculating Hazard Quotients (HQs) and the Hazard Index (HI) for each chemical. Chapters 1 and 5 discuss these calculations in more detail. The HI is calculated by summing the individual chemical HQs. Summing the HQs has the same limitations as stated above for dose additivity. Summing the HQs also treats all RfDs equally. The HQs are calculated from RfDs, which are derived from a single point on the dose/response curve. This calculation ignores the shape of the dose/response curve. The RfDs for each chemical are derived from animal experiments that contain a spectrum of toxic endpoints and disparate levels of confidence. There is a great deal of uncertainty attached to this estimation of risk for noncarcinogens.

Summing the slope factors for carcinogens has many of the same limitations previously stated. Summing the slope factors treats all carcinogens equally, regardless of their carcinogenicity classification. Known carcinogens, Class A, can be summed with probable (Class B) or possible (Class C) carcinogens. Slope factors are derived from the upper 95th percentile of the high to low dose extrapolation model. Upper 95th percentiles are not strictly additive. Summing slope factors can result in compounding conservatism, and it also increases uncertainty in the risk calculation.

Regulator Dialogue

The best method to use to avoid such uncertainties is to obtain toxicological information of the chemical mixture of interest. If this information cannot be obtained then the next solution is to concentrate on the noncarcinogens. As outlined in Risk Assessment Guidance for Superfund (RAGS) (USEPA 1989a), HQs for noncarcinogens should only be summed for those chemicals that affect the same target organ by the same mode of action. For carcinogens, there is no level of exposure that is considered safe; therefore, negotiations for carcinogens may be more difficult. An attempt should be made to sum slope factors for each individual carcinogen classification. That is, Class A carcinogens should only be summed with other Class A carcinogens, Class B with Class B, and Class C with Class C, Presently, acceptable risk levels for carcinogens range from 10^{-4} to 10^{-6} probability of developing cancer. Because Class C carcinogens are labeled as only possible carcinogens, it may be possible to negotiate an acceptable risk level for Class C carcinogens at 10^{-4}, whereas Class A carcinogens (i.e., known human carcinogens) and Class B carcinogens (i.e., probable human carcinogens) may have to be negotiated at a higher risk (e.g., 10^{-6} for Class A and 10^{-5} for Class B). Summing all of the classes together will probably result in having to negotiate at a higher risk level because the Class A and B carcinogens will be mixed in with the Class C compounds.

2.4.2 Data Gaps, Uncertainty, and Professional Judgement

Issue 1: Sources of Uncertainty

The sources of uncertainty for the risk characterization include those discussed above in Section 2.4.2. Data gaps in either the exposure or toxicity assessment impact the risk characterization because both of those components feed information into the final risk calculation.

Issue 2: Impact of Uncertainty on Risk Estimates

Missing information results in an incomplete risk assessment, which creates uncertainty in the overall findings of the assessment.

Issue 3: Means to Address Uncertainty

Filling the data gaps with reliable information can remove a great deal of the uncertainty in the risk assessment. Upgrading the models used in all steps of the assessment will also reduce the uncertainty in the risk calculation. The risk characterization component of the risk assessment is the section of the assessment where uncertainty is discussed.

Regulator Dialogue

A full and thorough analysis of uncertainty should be discussed so that the risk managers can make an informed decision.

2.5 Conclusion

The previous sections briefly discussed the issues involved with baseline risk assessments. The remaining chapters in this document will fully discuss each of these issues. Table 2.1 lists the issues and associated keywords to which they pertain, identifies the section of the document that discusses the particular issue, and identifies the EPA source documents where these issues are discussed. “

Table 2.1: Guide to Issues and Source Documents

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Alternative Toxicity Values	Acceptable Daily Intake (ADI)	7.2.2	USEPA 1989a
	Benchmark Dose	7.2.4	USEPA 1991a
	Lowest-Observed-Adverse-Effect-Level (LOAEL)	7.2.2, 7.2.3, 7.2.4	USEPA 1988a; USEPA 1988b; USEPA 1989a; USEPA 1991a
	No-Observed-Adverse-Effect-Level (NOAEL)	7.2.2, 7.2.3, 7.2.4, 7,3.1	USEPA 1988a; USEPA 1988b; USEPA 1989a; USEPA 1991a
	Reference Concentration (RfC)	7.1, 7.2.4	USEPA 1989a; USEPA 199 la
	Reference Dose (RfD)	7.1, 7.2.2,7.2.3, 7.2.4, 7.3.1	USEPA 1986a; USEPA 1988a; USEPA 1988b; USEPA 1989a; USEPA 1991a
	Study Design	7.2.2, 7.2.3,7.2.4, 7.3.1, 7.3.2	USEPA 1986b; USEPA 1988a; USEPA 1988b; USEPA 1989a; USEPA 1991a
	Threshold	7.2.4	USEPA 1991a
Default Factors vs. Site-Specific Data	Default Factors/Values	9.1,9.2.2,9.3.1, 9.3.2	USEPA 1989b; USEPA 1989c; USEPA 1991b; USEPA]991c
	Site-Specific	9.1, 9.2.2,9.3.1,9.3.2	USEPA 1986a; USEPA 1988c; USEPA 1989a; USEPA 1989b; USEPA 1989c; USEPA 1991b; USEPA 1992b

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Dose Additivity	Antagonism (antagonistic)	5.2.1, 5.2.3, 5.2.4, 5.3.1	USEPA 1986a; USEPA 1986c; USEPA 1989a; USEPA 1993
	Dose Additivity	5.1, 5.2.1, 5.2.3, 5.2.4, 5.2.6, 5.2.7, 5.3.1, 5.3.2	USEPA 1986a; USEPA 1986c; USEPA 1989a; USEPA 1993
	Hazard Index (HI)	5.1, 5.2.1, 5.2.3, 5.2.4, 5.2.7, 5.3.1, 5.3.2	USEPA 1986a; USEPA 1986c; USEPA 1989a; USEPA 1993
	Hazard Quotient (HQ)	5.1, 5.2.4, 5.2.7, 5.3.1, 5.3.2	USEPA 1989a; USEPA 1993
	Lowest-Observed-Adverse-Effect-Level (LOAEL)	5.1,5.2.5, 5.3.1	USEPA 1989a; USEPA 1993
	No-Observed-Adverse-Effect-Level (NOAEL)	5.1, 5.2.7, 5.3.1	USEPA 1989a; USEPA 1993
	Non-Threshold	5.1, 5.2.5	USEPA 1989a; USEPA 1991d
	Reference Concentration (RfC)	5.2.5	USEPA 1989a; USEPA 1991d; USEPA 1993
	Reference Dose (RfD)	5.1, 5.2.1, 5.2.4, 5.2.5, 5.2.7, 5.3.1, 5.3.2	USEPA 1986c; USEPA 1989a; USEPA 1991d; USEPA 1993

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Dose Additivity (continued)	Slope Factor	5.1, 5.2.4, 5.3.1, 5.3.2	USEPA, 1989a
	Synergism (synergistic)	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.3.1	USEPA 1986a, USEPA 1986c; USEPA 1986d; USEPA 1989a; USEPA 1993
	Threshold	5.1, 5.2.3, 5.2.4, 5.2.7	USEPA, 1986a, USEPA, 1989a; USEPA, 1993
Exposure Assessment Risk Descriptors	Absolute Worst Case	4.2.3, 4.3.1	USEPA 1989b
	Arithmetic Average	4.2.3, 4.2.5, 4.3.1	USEPA 1989c; USEPA 1992d; USEPA 1993
	Average Case	4.2.3, 4.3.1	USEPA 1989c
	Best Estimate	4.2.2, 4.2.3, 4.3.1	USEPA, 1986a; USEPA, 1989d
	Central Tendency	4.2.5, 4.3.1	USEPA, 1991d
	Confidence Limit	4.2.2, 4.3.1	USEPA, 1988c
	Equivalent Exposure Populations (EEP)	4.2.3, 4.3.1	USEPA 1988d
	Geometric Mean	4.2.5	USEPA, 1993
	High End	4.2.5, 4.3.1	USEPA 1991d
	Highest Individual Exposure	4.2.2 .4.3.1	USEPA 1986a

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Exposure Assessment Risk Descriptors (continued)	Maximally Impacted Residence	4.2.3, 4.3.1	USEPA 1988d
	Maximum Exposed Individual (MEI)	4.2.3, 4.2.5, 4.3.1	USEPA 1988d; USEPA 1992a
	Maximum Exposure Range	4.2.5, 4.3.1	USEPA 1992a
	Mid-Range	4.2.1, 4.3.1	USEPA 1990a
	Most Reasonable	4.2.5, 4.3.1, 4.3.2	USEPA 1993
	Overly Worst Case	4.2.3	USEPA 1989b
	Reasonable Maximum Exposure (RME)	4.1, 4.2.1, 4.2.3, 4.2.4, 4.2.5, 4.3.1, 4.3.2,	USEPA 1988e; USEPA 1989a; USEPA 1990a; USEPA 199lb; USEPA 1992d, USEPA 1993
	Reasonable Worst Case	4.1, 4.2.2, 4.2.3, 4.2.5, 4.3.1	USEPA 1986a; USEPA 1989b; USEPA 1989c; USEPA 1992a
	Standard Deviation	4.2.2, 4.3.1	USEPA 1988c
	Theoretical Upper Bounding Estimate (TUBE)	4.2.5, 4.3.1	USEPA 1992a
	Upper Confidence Limit	4.2.5, 4.3.1, 4.3.2	USEPA 1992a; USEPA 1993

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Exposure Assessment Risk Descriptors (continued)	Upper-Bound	4.2.1, 4.2.2, 4.2.3, 4.3.1	USEPA 1986a; USEPA 1989c; USEPA 1989d; USEPA 1990a
	Worst Case	4.1, 4.2.5, 4.3.1	USEPA 1992a
Exposure/Dose Calculation	Dose	3.2.2, 3.3.1, 3.3.2	USEPA 1992c
	Exchange Boundary	3.2.2, 3.3.1	USEPA 1989a; USEPA 1989b; USEPA 1991c; USEPA 1992a; USEPA 1992c
	Exposure	3.2.2, 3.3.1, 3.3.2	USEPA 1988c; USEPA 1989a; USEPA 1989b; USEPA 1991c; USEPA 1992a; USEPA 1992c
Exposure/Dose Terminology	Absorbed Dose	3.2.2	USEPA 1986d; USEPA 1989a; USEPA 1991c; USEPA 1992a: USEPA 1992c
	Administered Dose	3.2.2	USEPA 1989a; USEPA 1989b; USEPA 1989c; USEPA 199lc; USEPA 1992a; USEPA 1992c
	Applied Dose	3.2.2, 3.3.1, 3.3.2	USEPA 1989a; USEPA 1992a
	Delivered Dose	3.2.2	USEPA 1992a
	Dose	3.2.2, 3.3.1, 3.3.2	USEPA 1986a; USEPA 1989a; USEPA 1992a

Table 2.1: Guide to Issues and **Source Documents (continued)**

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Exposure/Dose Terminology (continued)	Exchange Boundary	3.2.2, 3.3.1, 3.3.2	USEPA 1986d; USEPA 1989a; USEPA 1989b; USEPA 1991c; USEPA 1992a
	Exposure	3.2.2, 3.3.1, 3.3.2	USEPA 1986a; USEPA 1986d; USEPA 1988c; USEPA 1989a; USEPA 1989b; USEPA 1989c; USEPA 1991c; USEPA 1992a; USEPA 1992c
	Exposure Dose	3.2.2	USEPA 1989c
	Exposure Point Concentration	3.2.2	USEPA 1989c
	Intake	3.2.2, 3.3.1, 3.3.2	USEPA 1986a; USEPA 1986d; USEPA 1989a; USEPA 1992a
	Internal Dose	3.2.2	USEPA 1992a
	Point of Contact	3.1, 3.3.1, 3.3.2	USEPA 1986d; USEPA 1989a; USEPA 1992a
	Potential Dose	3.2.2, 3.3.2	USEPA 1992a
Exposure Scenario Development	Land Use	8.2.3, 8.3.1, 8.3.2	USEPA 1989a; USEPA 1990a; USEPA 1991e
Impact of Summing HQs and Slope Factors	Antagonism (antagonistic)	5.2.1, 5.2.4, 5.2.7, 5.3.1	USEPA 1986c; USEPA 1989a; USEPA 1993

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Impact of Summing HQs and Slope Factors (continued)	Dose Additivity	5.2.1, 5.2.4, 5.2.7, 5.3.1	USEPA 1986c; USEPA 1989a; USEPA 1993
	Hazard Index (HI)	5.2.1, 5.2.4, 5.2.7, 5.3.1	USEPA 1986c; USEPA 1989a; USEPA 1993
	Hazard Quotient (HQ)	5.2.4, 5.2.7, 5.3.1	USEPA 1989a; USEPA 1993
	Lowest-Observed-Adverse-Effect-Level (LOAEL)	5.2.4, 5.3.1, 5.3.2	USEPA 1989a
	No-Observed-Adverse-Effect-Level (NOAEL)	5.2.4, 5.2.7, 5.3.1	USEPA 1989a; USEPA 1993
	Reference Dose (RfD)	5.2.1, 5.2.4, 5.2.7, 5.3.1	USEPA 1986c; USEPA 1989a; USEPA 1993
	Slope Factor	5.2.4, 5.3.1, 5.3.2	USEPA 1989a
	Synergism (synergistic)	5.2.1, 5.2.4, 5.2.7, 5.3.1	USEPA 1986c; USEPA 1989a; USEPA 1993
	Threshold	5.2.4, 5.2.7, 5.3.1	USEPA 1989a; USEPA 1993
Professional Judgement	Absolute Worst Case	4.2.3	USEPA 1989b
	Best Estimate	4.2.2	USEPA 1986a; USEPA, 1988c

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Professional Judgement (continued)	Data Gaps	10.2.2, 10.3.1, 10.3.2	USEPA 1989a; USEPA 1992a
	Exposure	8.3.1, 10.2.2	USEPA 1986a; USEPA 1989a; USEPA 199 lb; USEPA 1992a
	Hazard Index (HI)	5.3.2	USEPA 1986a
	Highest Individual Exposure	4.2.2	USEPA 1986a
	Land Use	8.3.1, 10.2.2	USEPA 1989a
	Overly Worst Case	4.2.3	USEPA 1989b
	Reasonable Maximum Exposure (RME)	4.2.3, 4.2.4, 4.3.1, 9.2.2	USEPA 1989a; USEPA 199 lb
	Reasonable Worst Case	4.2.2, 4.2.3	USEPA 1986a; USEPA 1989b
	Reference Dose (RfD)	7.2.2, 7.3.1	USEPA 1989a
	Study Design	7.2.2	USEPA 1989a
Radiation Calculations	Alpha Emitters/Particles/Radiation	6.3.1, 6.5.1, 6.6.2, 6.7	USEPA 1994a; USEPA 1994b
	Becquerel (Bq)	6.6.1, 6.6.2	NAS, 1990
	Beta Emitters/Particles/Radiation	6.3.1, 6.5.1, 6.7	USEPA 1994b

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Radiation Calculations (continued)	Curie (Ci, pCi)	6.5.4, 6.6.1, 6.6.2	NAS, 1990; USEPA 1989a; USEPA 1989e
	Gamma Emitters/Particles/Radiation	6.3.1, 6.5.1, 6.5.3, 6.7	USEPA 1989a; USEPA 1989e; USEPA 1994b
	Gray (Gy)	6.6.1, 6.6.2	NAS, 1990
	High LET	6.5.1, 6.5.2	NAS, 1990; USEPA 1994b
	Linear Energy Transfer (LET)	6.4.1, 6.5.1	USEPA 1994b
	Low LET	6.4.1, 6.5.1, 6.5.2, 6.5.3	NAS, 1990; USEPA 1994b
	Nonstochastic	6.1, 6.4.1	USEPA 1994b
	Progeny	6.3.2, 6.5.4, 6.7	USEPA 1989a; USEPA 1989e
	Rad	6.5.1, 6.5.2, 6.6.1, 6.6.2	NAS, 1990; USEPA 1994b
	Rem	6.4.1, 6.5,2, 6.5.4, 6.6.1, 6.6.2	NAS, 1990; USEPA 1989a; USEPA 1989e; USEPA 1994b
	Sievert (Sv)	6.6.1, 6.6.2	NAS, 1990

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Uncertainty	Communicating Uncertainty	4.2.2, 4.2.3, 4.3.2, 5.3.2, 7.2.1,9.2.2, 9.3.1, 10.2.1, 10.2.2, 10.3.2	USEPA 1986a; USEPA 1988c; USEPA 1988d; USEPA 1989a; USEPA 1989c; USEPA 1990a; USEPA 1991c; USEPA 1992a
	Impact of Uncertainty	10.2.2, 10.3.1	USEPA 1989a; USEPA 1990b; USEPA 1991c
	Means to Address Uncertainty	5.3.2, 7.3.1, 9.1, 9.2.2 10.2.2, 10.3.1	USEPA 1989a; USEPA 1990a; USEPA 1990b; USEPA 1991c; USEPA 1991fi USEPA 1992a
	Sources of Uncertainty	3.3.2, 4.2.3, 5.2.1, 5.3.1, 5.3.2,7.3.1, 9.2.2,9.3.1, 10.1, 10.2.2, 10.3.1	USEPA 1986d; USEPA 1989a; USEPA 1989b; USEPA 1989c; USEPA 1989d; USEPA 1990b; USEPA 199lc

Table 2.1: Guide to Issues and Source Documents (continued)

ISSUE	KEYWORDS	DOE GUIDANCE SECTION	SOURCE DOCUMENT
Uncertainty	Communicating Uncertainty	4.2.2, 4.2.3, 4.3.2, 5.3.2, 7.2.1,9.2.2, 9.3.1, 10.2.1, 10.2.2, 10.3.2	USEPA 19863; USEPA 1988c; USEPA 1988d; USEPA 1989a; USEPA 1989c; USEPA 1990a; USEPA 1991c; USEPA 1992a
	Impact of Uncertainty	10.2.2, 10.3.1	USEPA 1989a; USEPA 1990b; USEPA 1991c
	Means to Address Uncertain y	5.3.2, 7.3.1, 9.1, 9.2.2 10.2.2, 10.3.1	USEPA 1989a; USEPA 1990a; USEPA 1990b; USEPA l991c; USEPA 1991f; USEPA 1992a
	Sources of Uncertainty	3.3.2, 4.2.3, 5.2.1, 5.3.1, 5.3.2, 7.3.1, 9.2.2,9.3.1, 10.1, 10.2.2, 10.3.1	USEPA 1986d; USEPA 1989a; USEPA 1989b; USEPA 1989c; USEPA, 1989d; USEPA 1990b; USEPA 1991c

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USEPA. 1989c. Supplemental Manual to Risk Assessment Guidance for the Superfund Program. U.S. Environmental Protection Agency. U.S. EPA Region I. EPA 901/5-89401.

USEPA. 1989d. Exposure Assessment at Superfund Sites. U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Las Vegas, NV. EPA 600/X-89/381.

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